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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,415	09/12/2003	Andrew Vaillant	16051-8US	6654

20988 7590 06/23/2009

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EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,415	VAILLANT ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/12/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2009 has been entered.

Response to Amendment

The amendments to the claims filed September 5, 2008 have been acknowledged and entered. Claims 1, 2 and 14 are currently amended.

Status of the Claims

Claims 1, 2 and 14 are pending and under examination. Claims 3-13 and 15-42 have been cancelled.

Claim Rejections - 35 USC § 112

The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the claim is drawn to a method wherein said oligonucleotide is a randomer oligonucleotide **is withdrawn** pursuant Applicants amendment to claim 14.

Claim Rejections - 35 USC § 102

The rejection of claims 1-2, 14, 17-18, 21, 23, 27-28 and 30-32 under 35 U.S.C. 102(b) as being anticipated by Krieg et al. (US Patent 6,207,646, March 27, 2001) **is withdrawn** pursuant Applicants amendments.

New Claim Objections

Claim 1 is objected to because of the following informalities: The claim contains an spelling error in the new amendment, line 6 "CpG protion". Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not clear if all sequences meeting the requirements of the claims have anti-viral activity or the ability to be therapeutic against RSV and parainfluenza viruses. The claims lack written description for all **oligonucleotide of at least 20 nucleotides in length which are not complementary to any portion of the genomic sequence of RSV or parainfluenza virus, and**

are not complementary to any RSV or parainfluenza virus mRNA sequence to be capable of phrophylaxis or treatment of RSV and parainfluenza viruses.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice ... reduction to drawings .... or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

It is also noted that even the presence of multiple species with in a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in the performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997) (citing Smyth for support). Thus, when a claim covers a genus of inventions, the specification must provide sufficient written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed, or provided a function and a structure correlating with that function. However, in situations where the operability of other species than

those provided is uncertain, additional support may be required over that which would be required where greater certainty is present.

In the present case, the claimed invention is directed to a method for the prophylaxis or treatment of a RSV or parainfluenza virus infection in a subject comprising administering a therapeutically effective amount of a pharmacological acceptable oligonucleotide of at least 20 nucleotides in length, wherein said oligonucleotide comprises at least one phosphorothioated linkage, does not comprises an immune system interacting CpG portion, is not complementary to any portion of the genomic sequence of RSV or parainfluenza virus, and is not complementary to any RSV or parainfluenza virus mRNA sequence... The claim language is interpreted as any portion of a 20 nucleotide oligonucleotide, which can be as small as a base pair, can not be complementary to any portion (base pair or larger) of the sequence of RSV or parainfluenza virus or mRNA sequence. The claimed invention includes the administration of oligonucleotides of a single sequence however the claims can be interpreted as the administration of a combination of randomers as described in the application, and the administration of a composition comprising numerous copies of a single oligonucleotide sequence.

In the art, Cho et al. (Journal of Allergy and Immunology, Nov. 2001, Vol. 108, No. 5, pages 697-702) teaches two oligonucleotide sequences of 22 nucleotides in length, are tested for inhibiting the replication RSV. One of the sequences differs by only 2 nucleotides and that mutated sequence did not inhibit the replication of RSV as well as the other sequence. This illustrates that a small mutation or conservative substitution can change the effect and mode of action of the oligonucleotide. Therefore, the provided examples do not demonstrate possession

of the full genus of claimed sequences that have the required functions of anti-viral activity and phrophylaxis or treatment of RSV and parainfluenza viruses.

While the application discloses the efficacy of mixtures of unknown oligonucleotide sequences for the inhibition of parainfluenza viruses (PIV), the application does not identify any individual sequence effective against the virus. Therefore, in view of the indications of uncertainty in the art and the application as described above as to the importance of the oligonucleotide sequences on efficacy, and based on the lack of any disclosure of specific oligonucleotide sequences correlating to the efficacy of the claimed oligonucleotide mixtures against either of PIV or RSV, the application is found to have provided insufficient descriptive support for the claims, which read on the administration of any oligonucleotide for the treatment of infections by these viruses.

Structural differences in non-CpG oligonucleotides can affect immune responses as evidenced by McCluskie et al. (Vaccine, 2001, Vol. 19, pages 413-422). McCluskie compared immune responses in mice with three ODNs of 20 nucleotide in length, one CpG ODN and two non-CpG ODNs. The non-CpG ODNs were intended as a negative controls but one had an un-expected immunostimulatory effect while the other the non-CpG ODN did not have stimulatory effects (page 416, 1st column, 3rd paragraph). McCluskie teaches unpredictability of oligonucleotides sequences because sequence variations of non-CpG ODNs have functional differences of the ODNs immunostimulatory effects. Therefore, it is not clear that all sequences with the structure requirement of Applicants claims can perform the required functions of anti-viral activity and phrophylaxis. Applicant's disclosure lacks written description and examples

supporting that Applicants has possession of the full genus of claimed sequences that have the required functions.

The skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Double Patenting

Claims 1, 2 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-85 and 98-105 of copending Application No. 11/254,920.

Claims 23-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-85 and 98-105 of copending Application No. 10/969,812.

Claims 1-7 and 9-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-85 and 98-105 of copending Application No. 12/170,847.

Claims 1-5, 10 and 12-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-85 and 98-105 of copending Application No. 12/073,014.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to a method of treatment of a virus infection comprising administering a pharmacological acceptable oligonucleotide of at least 20 nucleotides in length, wherein said oligonucleotide comprises at least one phophorothioate linkage and is not complementary to a viral sequence and the antiviral activity of said oligonucleotide occurs principally by a sequence independent mode of action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M, T, Th, F 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Hurt/
Examiner, Art Unit 1648

/Zachariah Lucas/
Primary Examiner, Art Unit 1648

June 15, 2009